K082442 (1 of 1)

OCT 07 2008

510(k) Summary: MicroFuse™ Bone Void Filler

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory

Device Name: MicroFuse™ Bone Void Filler

Classification: Per 21 CFR §888.3045: Resorbable Calcium Salt Bone Void Filler. Class II. The Product Code is MQV. The Panel Code is 87.

Predicate(s): MicroFuse™ Bone Void Filler K071187

Device Description:
MicroFuse™ Bone Void Filler is a porous bone graft scaffold composed of bonded poly (lactide-co-glycolide) or poly(lactic acid) microspheres. MicroFuse™ is available with and without a combination of barium sulfate and calcium sulfate. MicroFuse™ is provided in a variety of shapes and sizes, in the form of granules, sheets, and pre-formed blocks. MicroFuse™ granules are designed to be gently packed into contained voids or defects. MicroFuse™ sheets are designed to be used with shallow bony defects, or as a bone graft onlay to cover a defect. MicroFuse™ blocks are designed to fill an entire defect. MicroFuse™ implants are available in short-term (ST), mid-term (MT), or long-term (LT) compositions.

Intended Use:
MicroFuse™ Bone Void Filler, combined with autograft or bone marrow aspirate, is intended for use in filling bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

Basis of Substantial Equivalence:
The MicroFuse™ Bone Void Filler is similar to the predicate device with respect to design, indications for use, principles of operation, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Globus Medical Inc.
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K082442
Trade/Device Name: MicroFuse™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 24, 2008
Received: September 25, 2008

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: K082442

Device Name: MicroFuse™ Bone Void Filler

Indications:

MicroFuse™ Bone Void Filler, combined with autograft or bone marrow aspirate, is intended for use in filling bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/7/08

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082442